K031734

JUL 1 2003

p. 1/2

BIOMET
ORTHOPEDICS, INC.

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Gary Baker
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587
Telephone: (574) 267-6639
Fax: (574) 372-1683

Proprietary Name: "Generation 4" Polished Femoral Hip Prosthesis

Common Name: Femoral Component for Cemented Use

Classification Name(s): Prosthesis, Hip, Semi-Constrained, Cemented, Metal/Polymer (888.3350)

Product Code(s): JDI

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

RX-90 Cemented Hip Prosthesis – Biomet Inc.(K023085).

Device Description: The Generation 4 Polished Femoral Hip Prosthesis is a series of implants meant to replace the patient's natural hip femoral neck and head due to disease or accident. The material is forged Co-Cr-Mo per ASTM F 799. They are designed for use with bone cement. General implant surfaces are highly polished and proximal and distal cement centralizers are offered for optimum stem placement within the canal. Stability within the cement mantle is enhanced by both a 4 mm medial collar designed to rest upon the calcar, and the bi-planer stem geometry which creates a wedge within the canal.

Implant sizing is graduated for different patient anatomies. Stem geometry is undersized to stated stem and instrument sizing so as to include a cement mantle. A trapezoidal neck design is offered on all sizes for increased range of motion. These devices accept a modular head used with associated acetabular reconstructive shells and liners. Contraindications are similar to comparable devices designed for replacement of the patient's natural hip femoral neck due to arthritic diseases or accident.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639 ■ FAX
574.267.8137 ■ E-MAIL
biomet@biomet.com

Indications for Use: The indications for use of the Generation 4 Polished Femoral Hip Prosthesis include:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid Arthritis.
3. Correction of functional deformity
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision procedures where other treatments or devices have failed.

The Generation 4 Polished Femoral Hip Prosthesis is intended for use in total hip arthroplasty, and is intended for cemented use only.

Summary of Technologies: The "Generation 4" Femoral Hip Prosthesis is manufactured from the same materials, utilizing the same manufacturing practices, and conforming to the same standards as other femoral hip prostheses cleared for cemented use.

Non-Clinical Testing: All 10 tested stems passed available ISO / ASTM as well as in house parameters.

Clinical Testing: No clinical testing was necessary for determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2003

Mr. Gary Baker
Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K031734
Trade/Device Name: "Generation 4" Polished Femoral Hip Prosthesis
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: June 3, 2003
Received: June 4, 2003

Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (IF KNOWN): K031734

Device Name: "Generation 4" Polished Femoral Hip Prosthesis

Indications for Use: The indications for use of the "Generation 4" Polished Femoral Hip Prosthesis include:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
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The "Generation 4" Polished Femoral Hip Prosthesis is intended for total hip arthroplasty, and is intended for cemented use only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109) OR Over-the-Counter Use_____ (Optional Format 1-2-96)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031734